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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,181	02/12/2002	Judith Aronhime	1662/56002	4579
26646	7590	11/17/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,181

Applicant(s)

ARONHIME ET AL.

Examiner

Brenda Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-45 is/are allowed.
- 6) ☒ Claim(s) 1-36 and 46-72 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date Jul 02, Jan 8 & 15, 2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-72 are pending in the application.

Change of Examiner

Note the change of Examiner in the present application. The Art Unit number is now (1624).

Election/Restrictions

The restriction requirement is herein withdraw, upon review and reconsideration of the restriction requirement made July 1, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 68, 69, 71 and 72 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for epilepsy, does not reasonably provide enablement for the prevention of seizures or depressing the central nervous system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance

present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant case, has claims which embrace polymorphic forms of oxcarbazepine.

HOW TO USE: Claims 71 and 72 are to a method of treating a disease, which is associated with the central nervous system and sodium channels. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the effectiveness of the claimed compounds. The scope of the method claims are not adequately enabled solely based on its inhibitory effect on the voltage sensitive sodium channels provided in the specification. Diseases and/or disorder(s) known to be associated with sodium channels include epilepsy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is difficult to treat many of the disorders claimed herein. Instant claim language embraces disorders not only for treatment but for **prevention** which is not remotely enabled. It is presumed in the prevention of the diseases and/or disorders claimed herein there is a way of identifying those people who may develop seizures. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.

No screening protocol(s) are ever described. Thus, no evidence of in vitro effectiveness is seen in the specification for one of the instantly claimed oxcarbazepine compounds. In general, pharmacological activity is a very unpredictable area. In cases

involving physiological activity "the scope of the enablement obviously varies inversely with the degree of unpredictability of the factors involved." In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Since this case involves unpredictable in-vivo physiological activities, the scope of the enablement given in the disclosure presented here was found to be low.

The specification has no working examples on the use of the oxcarbazepine compounds. There must be evidence to justify the contention that the claimed compounds can be useful in the treatment of diseases and/or disorders associated with "the central nervous system".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 1-32, 34-36 and 46-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claims 1, 5-11 and 58-72 are vague and indefinite in that it is not known what is meant by Oxcarbazepine Form B, which appears to be incomplete. It is neither an art recognized term or contains functional language to define it, the actual data does not appear in the claim.

b) Claims 2-4 are vague and indefinite in that it is not known what is meant by oxcarbazepine having a PXRD diffraction pattern as described in the specific peaks and in figure 1. It is believed that the applicants intended Oxcarbazepine Form B to differentiate this crystalline form.

- c) Claims 12, 16-20, 52 and 58-72 are vague and indefinite in that it is not known what is meant by Oxcarbazepine Form C, which appears to be incomplete. It is neither an art recognized term or contains functional language to define it, the actual data does not appear in the claim.
- d) Claims 13-15 are vague and indefinite in that it is not known what is meant by oxcarbazepine having a PXRD diffraction pattern as described in the specific peaks and in figure 2. It is believed that the applicants intended Oxcarbazepine Form C to differentiate this crystalline form.
- e) Claim 13 is vague and indefinite in that it does not end with a period indicating the end of the claim.
- f) Claims 21, 24-32 and 58-72 are vague and indefinite in that it is not known what is meant by Oxcarbazepine Form D, which appears to be incomplete. It is neither an art recognized term or contains functional language to define it, the actual data does not appear in the claim.
- g) Claims 22 and 23 are vague and indefinite in that it is not known what is meant by oxcarbazepine having a PXRD diffraction pattern as described in the specific peaks and in figure 3. It is believed that the applicants intended Oxcarbazepine Form D to differentiate this crystalline form.
- h) Claim 34 is vague and indefinite in that it is not known what is meant by Oxcarbazepine chloroform solvate Form E, which appears to be incomplete. It is neither an art recognized term or a functional language to define it, the actual data does not appear in the claim.

- i) Claims 35 and 36 are vague and indefinite in that it is not known what is meant by oxcarbazepine chloroform solvate having a PXRD diffraction pattern as described in the specific peaks and in figure 4. It is believed that the applicants intended Oxcarbazepine chloroform solvate Form E to differentiate this crystalline form.
- j) Claims 46-51 and 53-57 are vague and indefinite in that it is not known what is meant by Oxcarbazepine Form A, which appears to be incomplete. It is neither an art recognized term or a functional language to define it, the actual data does not appear in the claim.
- k) Claims 58-72 are vague and indefinite in that it is not known what is meant by Oxcarbazepine Form E, which appears to be incomplete. It is neither an art recognized term or a functional language to define it, the actual data does not appear in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 12, 21, 58-64, 68-69 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHINDLER, U.S. Patent No. 3,716,640. SCHINDLER teaches compounds, compositions and method of use of the oxcarbazepine compounds as claimed herein. See column 1, formula I. The definition of polymorph is such that a

polymorph is a specific **crystalline form** of a compound that can crystallize in different forms. However, a pharmaceutical composition of a polymorphic form of olanzapine in a non-solid no longer possesses its crystalline characteristics.

2. Claims 1, 12, 21, 33, 58-64 and 68-71 are rejected under 35 U.S.C. 102(b) as being anticipated by BOIREAU et al., U.S. Patent No. 5,658,900. BOIREAU teaches compounds, compositions and method of use of the oxcarbazepine compounds as claimed herein. See column 2, lines 25-32. The definition of polymorph is such that a polymorph is a specific **crystalline form** of a compound that can crystallize in different forms. However, a pharmaceutical composition of a polymorphic form of olanzapine in a non-solid no longer possesses its crystalline characteristics.

Claim Objections

3. Claim 37 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

4. Claims 37-45 are allowed. None of the prior art of record or a search in the pertinent art area teaches the process of preparing the oxcarbazepine chloroform solvate as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
November 15, 2004